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Washington, D.C. 20231

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

Re: ThermaChoice™ Uterine  
Balloon Therapy System  
FDA Docket No. 98E-0850

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,949,718. The application was filed on February 6, 1998, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. **The determination of the length of the regulatory review period should reference both U.S. Patent No. 4,949,718 and U.S. Patent No. 5,105,808.** Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Telephone inquiries regarding this matter should be directed to the undersigned at (703)306-3159.

A handwritten signature in black ink, appearing to read "Karin Tyson", written over a horizontal line.

Karin Tyson  
Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: OLSON & HIERL, LTD  
20 NORTH WACKER DRIVE  
36TH FLOOR  
CHICAGO IL 60606

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